MEDICAL INTERNATIONAL RESEARCH

OCT 4 2012

510 (k) Summary K 122.389

1. Applicant Information

Date Prepared:	March 16, 2012
Submitter:	MIR Medical International Research
Address:	Via del Maggiolino, 125
	00155 Roma – Italy
Contact Person:	Gerda Van Houts
Phone Number:	039-06-22754777

2. Device Information

Trade Name:	Minispir
Classification Name:	spirometer and oximeter

3. Identification of legally marketed device to which the submitter claims equivalence:

Company Name:	MIR Medical International Research
Device Name:	Minispir
510(k) number:	K082766

As Spirometer :
Regulation Number 868.1840

As oximeter:
Regulation Number 870.2700

4. Description of the device:
Minispir is a spirometer and pulse oximeter (optional) connected to a Personal Computer using a USB cable. The device measures a range of respiratory parameters, and the saturation of oxygen in the blood and the heart pulse rate.

5. Statement of Intended Use:
The **Minispir III** spirometer and pulse oximeter is intended to be used by either a physician, respiratory therapist or technician.
The device is intended to test lung function and can make:

- spirometry testing in people of all ages, excluding infants and neonates.
- oximetry testing in people of all ages.

It can be used in any setting.

6. Summary of the technological characteristics of the new device in comparison to those of the predicate device:

The new **Minispir** uses a new PCB (with a new microprocessor) and a different oximetry module. Also the external aspect and dimensions have slightly changed.

Spirometry function

The new **Minispir** has the

- same intended use
- same operating principle
- same turbine sensor
- same spirometry parameters
- same algorithms for spirometry parameters calculation

as the predicate **Minispir.**

Oximetry function

The new **Minispir** has the

- same intended use
- same operating principle
- same sensors
- same oximetry parameters (SpO2, pulse rate)
- same algorithms for oximetry parameters calculation

as the predicate **Minispir**.

Minispir uses a different oximetry module.

7. Brief discussion of the clinical and non clinical tests relied on for a determination of SE.

Testing was done to ensure that the **Minispir** would perform safely and accurately within the environments for which it is to be marketed.

Safety and environmental testing was conducted in accordance with EN 60601-1:2006 and EN 60601-1-2:2007. Electromagnetic compatibility (EMC), electrical, mechanical durability, safety (operator and patient), and temperature/humidity testing have been completed. The results demonstrates that the **Minispir** is in compliance with the guidelines and standards referenced and that it performs within its specifications.

Spirometry testing was performed according with American Thoracic Society (ATS) Standards. The results obtained were within the range of accuracy required by ATS.

A clinical investigation has been carried out to validate the new oximetry board. The results demonstrated required accuracy.

8. Conclusions

Based on these results, it is our determination that the device is safe, effective, and performs as well as the legally marketed device.

This summary on 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 4 2012

M.I.R. Medical International Research
Ms. Gerda Van Houts
Export Area Manager
Via Del Maggiolino 125
Rome, Italy 00155

Re: K122384
Trade/Device Name: Minispir- Spirolab III
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BZQ, DQA
Dated: September 11, 2012
Received: September 14, 2012

Dear Ms. Van Houts:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: **Minispir -Spirolab III**

Indications for Use: The MIR **Minispir** and **Spirolab III** spirometers and pulse oximeters are intended to be used by either a physician, respiratory therapist or technician.
The devices are intended to test lung function and can make:

- spirometry testing in people of all ages, excluding infants and neonates.
- oximetry testing in people of all ages.

They can be used in any setting.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K122384